ISOLATOR FOR USE IN SURGERY OR AS A CLEAN ROOM AND METHOD OF USING THE SAME

BACKGROUND

Many surgical procedures that are now being performed are known to generate air-borne particles that may have viral or bacterial contamination. If not properly contained, the operating room and surgical personnel present during these procedures are exposed to such contamination. This problem is particularly acute in the case of laser surgical procedures where a plume of material may include patient tissue and fluids as well as smoke and other gases. This invention relates to the containment and neutralization of such air-borne contaminants by creating a barrier of filtered air between the local area of the surgical procedure and the surgical personnel, patient, and operating room environment. Further, it is anticipated that the method and apparatus of this invention will find uses outside of the medical field such as with the assembly and servicing of equipment that is sensitive to environmental contamination.

Although medical science and technology is growing at an exponential rate, the ability of surgical procedures and other medical treatments to cure is impeded by our inability to prevent infection. Common procedures which have been used to minimize the risk of infection include the sterilization of all instruments and materials which come in contact with the wound, chemically sterilizing the patient's skin at the site of the procedure, and thoroughly scrubbing the surgical team before donning sterilized caps, gowns, masks and gloves. In addition, the air in the operating room air is constantly changed and filtered. Nevertheless, even when these precautions and others are taken, a significant percentage of supposedly clean operations result in wound infections.

One of the problems is that disease organisms are ubiquitous in the operating room air, on the skin, and in the respiratory and gastrointestinal tracts of the patient and every other person in the room. For example, it has been determined that 30,000 to 60,000 particles are shed each minute from each person in the operating room. Bacterial contaminants are released into the atmosphere from the skin, by breathing and passing gas, and from the urinary tracts of those present. Further, potentially infectious particles or organisms fall from the hair, and pass through damp gowns and masks and through punctured gloves to create additional hazards of contamination and infection.

While improved methods for preventing contamination and infection are being found, it is becoming increasing clear that even the most minor exposure to contaminants may be sufficient to generate infection or spread disease. More particularly, there are certain types of surgical procedures that experience a higher than normal rate of infection, such as the implantation of prosthetic devices or artificial organs. The dose of bacteria necessary to invade the wound and cause an infection is reduced when foreign matter, such as an implanted device, is introduced into the body. Repeated experimental and clinical studies have proven that the mere presence of a foreign body can seriously impede the human body's immune system. Over 50,000 bacteria may be required to cause a surgical wound infection in normal operations whereas only 100 bacteria can cause infection when an implant device, even though inert, is introduced. In some implant surgical procedures, it has been theorized that a single bacterium may be all that is necessary to cause a deep wound infection.

In the case of laser surgical procedures, the risk of contamination is compounded by the generation of a laser plume containing smoke and other debris during the operation. Further, the added risk of contamination due to this plume is not limited to contamination of the wound site of the patient. Due to its air borne nature, if this plume is not contained and evacuated from the area around the wound site, such air-borne contaminants may settle on any exposed surface in the operating room as well as in the eyes and the respiratory tracts of the patient and surgical personnel.

The most common type of laser device being used in surgical procedures is a CO_2 laser emitting at a wavelength of just under 11,000 nanometers. During its use, the energy of this laser is absorbed by cellular water causing it to be heated and vaporized, and ultimately causing cells to rupture. This vaporization creates a plume of materials that can include water, smoke, and other gases, carbonized cell fragments, cellular, or viral DNA, and in some cases live cells and active viruses. With increased awareness of such highly communicable diseases such as AIDS, such contamination by such air borne materials is highly undesirable.

Therefore it is an object of this invention to provide a double chambered surgical isolator in which surgical procedures may be performed and which will contain any smoke and airborne particles generated by that procedure, and an air handling unit which is capable of maintaining a flow of clean filtered into the surgical isolator, evacuating smoke and airborne particles, and cleansing the evacuated air for recirculating it back into the surgical isolator.

The surgical isolator is composed of an inner enclosure and chamber in which the surgical procedure is carried out and an outer enclosure and chamber enveloping the inner enclosure. The air-handling unit provides filtered air to the outer chamber while simultaneously evacuating air from the inner chamber such that positive pressure is maintained in the outer chamber while a negative pressure is maintained in the inner chamber. Any leakage in the walls of the inner enclosure will result in a flow of clean filtered air from the outer to the inner chamber. Any leakage in the walls of the outer enclosure will result in a flow of clean filtered air into the operating room. Inner enclosure walls are provided with openings through which filtered air passes into the inner chamber from the outer chamber. Arm ports are provided in both the inner and outer enclosure walls to allow surgical personnel to perform the procedure on the patient. Attached at the periphery of the arm ports are tapered sleeves with elastic bands, such that when the sleeve is not in use, the flow of air through the sleeve is restricted.

An instrument lock, attached to the outer enclosure, is provided with removable doors to the inner chamber and to the operating room environment respectively. The door separating the instrument lock from the inner chamber is provided with openings to allow a flow of filtered air from the outer chamber into the instrument lock and from the instrument lock into the inner chamber. Instruments required during the procedure may be introduced into the inner chamber through the instrument lock either before or during a surgical procedure.

The air handling unit of this invention is capable of providing a flow of filtered air to the outer chamber while simultaneously evacuating smoke and contaminated air from the inner chamber. The air handling unit is equipped with means for neutralizing any viruses or bacteria present in the smoke or airborne particles and with appropriate filters for removing all such particles from the air so that it can be recycled back into the outer chamber.